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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Ex. Rel SHAWN L. SWINNEY,	:	C.A.No. 05cv3019
Plaintiffs,	:	**FILE *IN CAMERA* AND UNDER SEAL**
vs.	:	
BIOLIFE PLASMA SERVICES, L.P., a Pennsylvania Limited Partnership, and BAXTER HEALTHCARE CORPORATION, a Delaware Corporation,	:	JURY TRIAL DEMANDED
Defendants.	:	

FILED
JUN 23 2005
MICHAEL E. KUNZ, Clerk
By _____ Dep. Clerk

COMPLAINT FOR DAMAGES AND OTHER RELIEF UNDER THE *QUI TAM* PROVISIONS OF THE FALSE CLAIM ACT AND THE CALIFORNIA FALSE CLAIMS ACT, DELAWARE FALSE CLAIMS AND REPORTING ACT, FLORIDA FALSE CLAIMS ACT, ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT, LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, TENNESSEE MEDICAID FALSE CLAIMS ACT, TEXAS MEDICAID FRAUD PREVENTION STATUTE, VIRGINIA FRAUD AGAINST TAXPAYERS ACT, AND THE DISTRICT OF COLUMBIA'S HAWAII'S, MASSACHUSETTS' AND NEVADA'S FALSE CLAIMS PROVISIONS

I. JURISDICTION AND VENUE

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from the conduct of defendants Biolife Plasma Services, L.P. and Baxter Healthcare Corporation in causing false claims to be presented under the federal Medicare, Medicaid and CHAMPUS programs, and, upon information and belief, to the United States Department of Health and Human Services.

2. Medicare is a federally-funded health insurance program primarily for the elderly. Medicaid is a state and federal assistance program to provide payment of medical expenses for low-income patients. The Civilian Health and Medical Program of the Uniform Services

("CHAMPUS") is a program of medical insurance benefits provided by the federal government to individuals with family affiliations to the military services.

3. This *Qui Tam* claim arises under the provisions of the federal False Claims Act, 31 U.S.C. § 3729, *et seq.* This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732.

4. Personal jurisdiction and venue for this action are predicated on 31 U.S.C. § 3732(a) which provides that "any action brought under § 3730 may be brought in any judicial district in which the defendant, or in the case of multiple defendants, any one defendant can be found, resides, transacts business or in which any act prescribed by § 3729 occurred." Defendant Baxter Healthcare Corporation transacts substantial business in the Eastern District of Pennsylvania.

5. This Court also has supplemental jurisdiction over the California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Louisianna, Massachusetts, Nevada, Tennessee, Texas, and Virginia Qui Tam claims pursuant to 28 U.S.C. §1367 which provides that "in any civil action of which the district courts have original jurisdiction, the district court shall have supplemental jurisdiction over all claims that are so related to claims in action in such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution."

6. Under the False Claims Act, this Complaint is to be filed *In Camera*, remain under seal for a period of at least sixty (60) days and shall not be served on the defendants until the Court so orders. The government may elect to intervene and proceed with the action within sixty (60) days after it receives both the Complaint and the material evidence and information.

7. As required under the False Claims Act, the Relator, plaintiff herein, has provided to the Attorney General of the United States and the United States Attorney for the Eastern

District of Pennsylvania simultaneously with the filing of this Complaint, a statement of all material evidence and information related to the Complaint. This disclosure statement supports the existence of false claims by defendants in the Medicare, Medicaid and CHAMPUS programs.

II. PARTIES

8. *Qui Tam* plaintiff Shawn Swinney is a citizen and resident of the Commonwealth of Pennsylvania and brings this action on behalf of the United States of America.

9. Plaintiff Shawn Swinney is a current employee of defendant Biolife Plasma Services, L.P., working as an acting interim manager of their source plasma collection and manufacturing facility in Harrisburg, Pennsylvania. Mr. Swinney has personal knowledge of the conduct of Biolife Plasma Services' employees resulting in false claims asserted by Biolife Plasma Services, L.P. and Baxter Healthcare Corporation to the federal government and its agencies and programs.

10. Plaintiff Shawn Swinney has provided the Attorney General of the United States and the United States Attorney for the Eastern District of Pennsylvania simultaneously with the filing of this Complaint, a Statement of All Material Evidence and Information related to the Complaint. This disclosure statement supports the existence of false claims made by defendants to the Medicare, Medicaid and CHAMPUS PROGRAMS, as well as those made to the United States of America, Department of Health and Human Services.

11. Defendant Biolife Plasma Services, L.P. (hereinafter referred to as "Biolife"), upon information and belief, is a limited partnership duly organized and authorized to conduct business under the laws of the Commonwealth of Pennsylvania.

12. Defendant Baxter Healthcare Corporation is a corporation duly organized and authorized to conduct business under the laws of the State of Delaware.

13. Defendant Biolife Plasma Services, L.P. is a wholly-owned subsidiary of defendant

Baxter Healthcare Corporation.

III. ALLEGATIONS

14. Defendant Biolife owns and operates several plasma collection facilities across the United States and is licensed by the Center for Biologics Evaluation (CBER) of the Food and Drug Administration (FDA) to collect source plasma as that term is defined under 21 C.F.R. § 640.30(b), with a CBER license number 1640. Biolife owns and operates plasma collection facilities in Harrisburg and State College, Pennsylvania.

15. Biolife distributes the source plasma it collects to Baxter Healthcare Corporation, including its Baxter Bioscience division, for use in manufacturing licensed injectable products, such as vaccines. Biolife also distributes source plasma to third-party buyers.

16. Collection of the source plasma is regulated by the Food and Drug Administration, Title 21, Code of Federal Regulations, Parts 210-211 and 600-680.

17. Specifically, 21 C.F.R. §§ 640.60-640.76 govern the collection of plasma by plasmapheresis as that term is defined by 21 C.F.R. § 640.65.

18. Under 21 C.F.R. § 210.2, defendant Biolife is subject to Current Good Manufacturing Practice regulations under 21 C.F.R. §§ 600-680 with respect to the collection of source plasma.

19. Under 21 C.F.R. § 210.2, defendant Baxter Healthcare Corporation is subject to Current Good Manufacturing Practice regulations under 21 C.F.R. §§ 211 through 226 with respect to drugs and §§ 600 through 680 with respect to biologic products for human use.

20. Under 21 C.F.R. § 640.67 and § 610.40, Biolife is required to perform certain testing for communicable diseases upon the source plasma which it collects, including the Human immunodeficiency virus, Types 1 and 2; the Hepatitis B virus and the Hepatitis C virus.

21. Under 21 C.F.R. § 606.100, Biolife had to institute "standard operating procedures" for its personnel which were compliant with the provisions of § 640 to govern the collection, processing, testing, storage and distribution of the plasma it collected. Additionally, Biolife had to have in place standard operating procedures for its personnel in accordance with § 610.46 with respect to testing of the plasma.

22. Biolife had an obligation to report all product deviations - deviations from good manufacturing practice, applicable regulations, applicable standards or established specifications that may affect the safety, purity or potency of the product - under either 21 C.F.R. § 600.14 or § 606.171.

23. During 2003 and through the present, Biolife committed several deviations from the Current Good Manufacturing Practice regulations at its Harrisburg, PA facility during the collection of plasma, including, without limitation, the following:

(a) Falsification of donor qualification records;

(b) Failure to conduct appropriate pre-collection medical screening;

(c) Failure to properly staff quality control;

(d) Failure to follow up on laboratory test results for donors;

(e) Failure to follow standard operating procedures for the collection and destruction of collected/stored units of plasma from a donor who has tested positive to HIV, HCV or syphilis;

(f) Failure to notify manufacturers who purchased the collected plasma of positive specimens;

(g) Failure to file Blood Product Deviation reports with the U.S. Food and Drug Administration in a timely manner;

(h) Failure to file Blood Product Deviation reports with the U.S. Food and Drug Administration;

(i) Failure to maintain the appropriate records for each donor;

(j) Failure to provide appropriate training to personnel;

(k) Failure to have in place standard operating procedures for certain functions within the collection and distribution of plasma;

24. As a result of the deviations from the Current Good Manufacturing Practice regulations, source plasma from a donor who tested positive for syphilis was distributed by Biolife to manufacturers, including Baxter Healthcare Corporation, for use in the manufacture of injectable biological products, such as vaccines.

25. Upon information and belief, as a result of the deviations from the Current Good Manufacturing Practice regulations, source plasma from donors who tested positive for HIV, HCV and HBV were distributed by Biolife to manufacturers, including Baxter Healthcare Corporation, for use in the manufacture of injectable biological products, such as vaccines.

26. Upon further information and belief, plasma colleted by Biolife and which came from donors discovered by Biolife to be HIV positive, HCV positive, HBV positive and/or infected with syphilis was combined with other plasma from which commercial plasma products were prepared by Baxter Healthcare Corporation.

27. At all times relevant hereto, management at Biolife was aware of the deviations from Current Good Manufacturing Practice regulations at the Harrisburg, PA facility and ignored the same, allowing the contaminated and adulterated plasma products collected at the Harrisburg facility to be distributed, knowing that products would be used as source plasma in plasma-based products such as vaccines and antibody therapies - many of which would be manufactured by its

parent corporation, Baxter Healthcare Corporation.

28. As a result of the failure to follow the Current Good Manufacturing Practice regulations in the collection and distribution of the source plasma, Biolife distributed source plasma to Baxter Healthcare Corporation which was adulterated under 21 U.S.C. § 351 and in violation of 21 U.S.C. § 331.

29. At all times relevant hereto, defendant Baxter Healthcare Corporation knew that its plasma collection facility at Harrisburg, PA operated by its subsidiary defendant Biolife was not operating in conformance with Current Good Manufacturing Practice regulations and that the source plasma it accepted from Biolife was adulterated under 21 U.S.C.§ 331 yet used the adulterated source plasma to produce plasma-based products which it, in turn, distributed in exchange for federal monies through Medicare, Medicaid, CHAMPUS and, upon information and belief, the Department of Health and Human Services.

30. Consequently, source plasma which was adulterated has been integrated into manufactured biological products purchased by Medicare, Medicaid, CHAMPUS and the United States Department of Health and Human Services.

COUNT I
VIOLATION OF THE FALSE CLAIMS ACT, 31 U.S.C. § 3729

31. Plaintiff-relator repeats the allegations contained in paragraphs 1 through 30 herein by this reference and realleges the same as if set out in full.

32. From 2003 through the present, Biolife's failure to follow Current Good Manufacturing Practice regulations at its Harrisburg, PA facility and Baxter Healthcare Corporation's failure to follow Current Manufacturing Practice regulations in the manufacture of its plasma-based products has resulted in the sale of plasma-based products by Baxter Healthcare

Corporation to the Federal Government which contain source plasma which was adulterated under 21 U.S.C. § 351 and which likely was positive for communicable diseases such as syphilis, HIV, HCV and HBV.

33. Defendants Biolife and Baxter Healthcare Corporation knew of the contaminated source plasma and, consequently, the adulterated plasma-based products sold to the Federal Government yet defendants distributed the adulterated source plasma and adulterated plasma-based products in violation of 21 U.S.C. § 331 and submitted claims to the Federal Government for payment for the adulterated plasma-based products which did not conform to the FDA regulations.

34. As such, defendants Biolife and Baxter Healthcare Corporation submitted false claims to the United States and are liable under 31 U.S.C.A. § 3729(a)(1), (2) and (3).

35. The United States, its fiscal intermediaries and state Medicaid programs were unaware of defendants conspiracies or the falsity of their records, statements and claims, and as a result, continue to pay Medicare, Medicaid and CHAMPUS reimbursements that they would not otherwise have paid.

36. The United States Department of Health and Human Services was unaware of the false statements made by defendant Baxter Healthcare Corporation regarding its claim for payment for smallpox vaccines and paid for the same.

WHEREFORE, Plaintiff demands judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the False Claims Act, this Court enter judgment in Plaintiff's favor and against defendants Biolife Plasma Services, L.P. and Baxter Healthcare Corporation in an amount equal to three (3)

times the amount of damages that the United States has sustained because of defendants actions, plus a civil penalty of not less than $5,000 nor more than $10,000 for each violation of 31 U.S.C. § 3729;

b. That Plaintiff-Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and/or any other applicable provision of the law;

c. That Relator be awarded all costs and expenses in this action;

d. That Plaintiff-Relator have such other and further relief as to this Court seems just and proper;

e. A jury trial on all issues so triable;

COUNT II
VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

37. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 36 of this Complaint and realleges the same herein as if set out in full.

38. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of California in violation of CAL. GOV. CODE § 12651(a)(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which California's state Medicaid program made payments.

39. California's state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid

reimbursement they would not otherwise have paid.

40. The California state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the California False Claims Act that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more than three times the amount of damages that California has sustained because of defendants' actions, plus a civil penalty of not more than $10,000 for each violation of CAL. GOV. CODE § 12651(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to CAL. GOV. CODE § 12652(g)(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable;

COUNT III
VIOLATION OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT

41. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 40 of this Complaint and realleges the same herein as if set out in full.

42. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter

Healthcare Corporation asserted false claims to the State of Delaware in violation of DEL. CODE ANN.TIT. 6, § 1201(a)(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Delaware's state Medicaid program made payments.

43. Delaware's state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

44. The Delaware state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Delaware False Claims and Reporting Act that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more than three times the amount of damages that Delaware has sustained because of defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of DEL. CODE ANN. TIT. 6 § 1201(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to DEL. CODE ANN. TIT 6 § 1205(a) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable;

COUNT IV
VIOLATION OF D.C. CODE ANN. §§ 2-308.13-.15

45. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 44 of this Complaint and realleges the same herein as if set out in full.

46. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the District of Columbia in violation of D.C. CODE ANN. § 2-308.14(a)(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which the District of Columbia's Medicaid program made payments.

47. The District of Columbia's Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

48. The District of Columbia's Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the District of Columbia's false claims provisions that this Court enter judgment in Plaintiffs' favor and

against defendants in an amount equal to not less than two times and not more than three times the amount of damages that the District of Columbia has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of D.C. CODE ANN. § 2-308.14(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to D.C. CODE ANN. § 2-308.15(f)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable;

COUNT V
VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

49. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 48 of this Complaint and realleges the same herein as if set out in full.

50. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of Florida in violation of FLA. STAT. ANN. § 68.082(2)(a)(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Delaware's state Medicaid program made payments.

51. Florida's state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for

payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

52. The Florida state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Florida False Claims and Reporting Act that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more than three times the amount of damages that Florida has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of FLA. STAT. ANN. TIT. § 68.082(2)(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to FLA. STAT. ANN. § 68.085(1)-(2) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable;

COUNT VI
VIOLATION OF HAWAII REV. STAT. §§ 661-21-661-29

53. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 52 of this Complaint and realleges the same herein as if set out in full.

54. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of Hawaii in violation of HAW. REV. STAT. §§ 661-21(a)(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Hawaii's state Medicaid program made payments.

55. Hawaii's state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

56. The Hawaii state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Hawaii false claims provisions that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more than three times the amount of damages that Hawaii has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of HAW. REV. STAT. § 661-21(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to HAW. REV. STAT. § 661-27(a) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable;

COUNT VII
VIOLATION OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

57. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 56 of this Complaint and realleges the same herein as if set out in full.

58. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of Illinois in violation of 740 ILL. COMP. STAT. 175/(a)(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Illinois' state Medicaid program made payments.

59. Illinois' state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

60. The Illinois state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Illinois Whistleblower Reward and Protection Act that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more

than three times the amount of damages that Illinois has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of 740 ILL. COMP. STAT. 175/3(a)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to 740 ILL. COMP. STAT. 175/4(d)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable;

COUNT VIII
VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

61. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 60 of this Complaint and realleges the same herein as if set out in full.

62. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of Louisiana in violation of LA. REV. STAT. ANN. § 46:438.3(C) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Louisiana's state Medicaid program made payments.

63. Louisiana's state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid

reimbursement they would not otherwise have paid.

64. The Louisiana state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Louisiana Medical Assistance Programs Integrity Law that this Court enter judgment in Plaintiffs' favor and against defendants in an amount not to exceed three times the amount of damages that Louisiana has sustained because of defendants' actions, plus a civil penalty of not more than $10,000 for each violation of LA. REV. STAT. ANN. § 46:438.3(C);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to LA. REV. STAT. ANN. § 46:438.3(A) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable;

COUNT IX
VIOLATION OF MASS. GEN. LAWS CH. 12, §5A-5Q

65. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 64 of this Complaint and realleges the same herein as if set out in full.

66. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the Commonwealth of Massachusetts in violation of MASS. GEN. LAW CH. 12, §5B(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Massachusetts' state Medicaid program made payments.

67. Massachusetts' state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

68. The Massachusetts state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of Massachusetts' false claims provisions, that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to three times the damagess that Massachusetts has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of MASS. GEN. LAWS. CH. 12 §5B(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to MASS. GEN. LAWS. CH. 12 §5F(1)-(3) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable.

COUNT X
VIOLATION OF NEV. REV. STAT. § 357.010-.250

69. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 68 of this Complaint and realleges the same herein as if set out in full.

70. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of Nevada in violation of NEV. REV. STAT. § 357.014(1)(c) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Nevada's state Medicaid program made payments.

71. Nevada's state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

72. The Nevada state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Nevada's false claims

provisions that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal three times the amount of damages that Nevada has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of NEV. REV. STAT. § 357.014(1)(c);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to NEV. REV. STAT. § 357.210(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable.

COUNT XI
VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT

73. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 72 of this Complaint and realleges the same herein as if set out in full.

74. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of Tennessee in violation of TENN. CODE ANN.§ 71-5-182(a)(1)(C) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Tennessee's state Medicaid program made payments.

75. Tennessee's state Medicaid program was unaware that the source plasma and

plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

76. The Tennessee state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Tennessee Medicaid False Claims Act that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more than three times the amount of damages that Tennessee has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of TENN. CODE ANN. § 71-5-182(a)(1)(C);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to TENN. CODE ANN. § 71-5-183(c)(1) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable.

COUNT XII
VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION STATUTE

77. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 76 of this Complaint and realleges the same herein as if set out in full.

78. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the State of Texas in violation of TEX. HUM. RES. CODE ANN. § 36.002(8) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Texas' state Medicaid program made payments.

79. Texas' state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

80. The Texas state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Texas Medicaid Fraud Prevention Statute that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to two times the damages that Texas has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that results in injury to an elderly person, a disabled person, or a person

younger than 18 years of age, or not less than $1,000 and not more than $10,000 for each violation of TEX. HUM. RES. CODE ANN. § 36.002(8) that does not result in injury to a person;

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to TEX. HUM. RES. CODE § 36.110 and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable.

COUNT XIII
VIOLATION OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT

81. Plaintiff/Relator repeats the allegations contained in paragraphs 1 through 80 of this Complaint and realleges the same herein as if set out in full.

82. From at least 2003 continuing to the present, defendant Biolife and defendant Baxter Healthcare Corporation asserted false claims to the Commonwealth of Virginia in violation of VA. CODE ANN. 8.01-216.3(A)(3) when they knowingly, or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, sold adulterated source plasma and adulterated plasma-based products for which Virginia's state Medicaid program made payments.

83. Virginia's state Medicaid program was unaware that the source plasma and plasma-based products it purchased from defendants was adulterated and that the claims asserted for payment by defendants were false, and as a result they have paid, and continued to pay Medicaid reimbursement they would not otherwise have paid.

84. The Virginia state Medicaid program has suffered damages as a result of its payment of false and fraudulent claims.

WHEREFORE, Plaintiffs demand judgment against defendants Biolife and Baxter Healthcare Corporation as follows:

a. That by reason of the aforementioned violations of the Virginia Fraud Against Taxpayers Act that this Court enter judgment in Plaintiffs' favor and against defendants in an amount equal to not less than two times and not more than three times the amount of damages that Virginia has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of VA. CODE ANN. § 8.01-216.3(A)(3);

b. That Relator, as *Qui Tam* Plaintiff, be awarded the maximum amount pursuant to VA. CODE ANN. § 8.01-216.7(A) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs in the prosecution of this suit; and

d. That Plaintiff and Relator have such other and further relief that this Court deems just and proper;

e. A jury trial on all issues so triable.

Respectfully submitted,

SHELLER, LUDWIG & BADEY, P.C.

By: _____

Stephen A. Sheller, Esq.
1528 Walnut Street, 3rd Floor
Philadelphia, PA 19102
(215) 790-7300

CERTIFICATE OF SERVICE

I, Stephen A. Shelly, hereby certify that a true and accurate copy of the foregoing Complaint has been served this the 23rd day of June, 2005, upon the following:

VIA HAND DELIVERY
Patrick L. Meehan, United States Attorney
c/o Virginia Gibson, Chief, Civil Division
United States Attorney's Office
615 Chestnutt Street, Suite 1250
Philadelphia, PA 19106-4476

VIA CERTIFIED MAIL
Honorable Alberto Gonzales
Attorney General
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530-0001

This the 23rd day of June, 2005.

SHELLER, LUDWIG & BADEY, P.C.

By: _____
Stephen A. Sheller